PATENT
Customer No. 22,852
Attorney Docket No. 3804.1596

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Manfred BOHN et al.	)	Group Art Unit: 1614
	)	
Application No.: 09/077,194	)	Examiner: V. Kim
	)	
Filed: May 26, 1998	)	
	)	
For: USE OF 1-HYDROXY-2-PYRIDONES FOR THE TREATMENT OF SEBORRHEIC DERMATITIS	)	

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

In support of the Notice of Appeal filed October 16, 2002, and pursuant to 37 C.F.R. § 1.192, Appellants present three copies of their brief and a check in the amount of $320.00 for the fee under 37 C.F.R. § 1.17(c). Please grant any extensions of time required to enter this Appeal Brief and charge any additional required fees to our Deposit Account No. 06-0916. Applicants also file herewith an Amendment under 37 C.F.R. § 1.116 and respectfully request entry thereof.

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Washington, DC 20005
202.408.4000
Fax 202.408.4400
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I. Real Party in Interest

The real party in interest is Aventis Pharma Deutschland GmbH, Assignee of the present application.

II. Related Appeals and Interferences

To the best of the undersigned's knowledge, there are no related appeals or interferences known to Appellants, the Appellants' legal representative, or Assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

III. Status Of Claims

Claims 38-42, 48, and 53-66 are currently pending, as amended. Claims 38, 39, 53, 59, 65, and 66 are independent. Remaining claims have been cancelled without prejudice or disclaimer.

IV. Status Of Amendments

The Amendment filed April 24, 2002, has been entered. Appendix A presents the claims in the form pending after that Amendment. Applicants file herewith an Amendment under 37 C.F.R. § 1.116, solely to correct minor errors. If that Amendment is entered, the reader is directed to Appendix B for the claims on appeal.

V. Summary Of Invention

Appellants have discovered an effective treatment for seborrheic dermatitis that can be tolerated well by patients. In one embodiment of the claimed invention, antifungal compounds known as 1-hydroxy-2-pyridones have been combined in a low pH shampoo, which has been shown to treat seborrheic dermatitis. *See e.g.* Example 8 on page 12 of the specification. This result is surprising for at least three reasons.

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First, many of these 1-hydroxy-2-pyridones demonstrate anti-inflammatory and anti-bacterial effects, in addition to antifungal effects, these effects being useful in the treatment of seborrheic dermatitis. *See id.* at page 1, lines 30-37, and page 2, lines 6-12. Second, successful treatment of seborrheic dermatitis has been shown with the brief application of these shampoos. *See id.* at page 12, lines 9-21. Conventional treatments require application of a composition that will remain on the afflicted skin for as long as possible, rather than be rinsed away as with a shampoo. *See id.* at page 1, lines 26-28. Third, the low pH shampoo is a less-irritating delivery platform, compared to higher pH, alkaline shampoos. Alkaline shampoos are known, for example, to sting the eyes and cause tearing. Consequently, low pH shampoos can be more easily tolerated by patients. The pending claims employ several strategies to cover the inventive subject matter.

Independent claims 38, 39, 53, 59, 65, and 66 each relate to methods of treating seborrheic dermatitis in a human or animal patient. Specific support for such treatment appears, among other places, in the specification at page 2, line 25 to page 3, line 20, and page 12, lines 9-21. The method comprises administering a composition comprising at least one 1-hydroxy-2-pyridone, which may be present in free form or as a pharmaceutically acceptable salt. The 1-hydroxy-2-pyridones appear on pages 2-3, and specific examples are mentioned, among other places, on page 4, lines 10-26. Salts thereof are mentioned on page 4 at lines 31-32, and elsewhere. The compositions of the claimed methods also comprise at least one surfactant chosen from anionic, cationic, nonionic and amphoteric surfactants, such as those mentioned in the specification starting on page 5, line 37, continuing through page 7, line 34.

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Independent claims 38 and 65 comprise an active component consisting essentially of at least one 1-hydroxy-2-pyridone. Support for compositions containing only 1-hydroxy-2-pyridones as the active component can be found, among other places, in the specification at page 1, lines 34-37 and at page 2, lines 6-12.

In independent claims 39, 59, and 66, the radical Ar is a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether. Support for this bicyclic system can be found, among other places, in the specification at page 3, lines 31-34.

The compositions of some of the claimed methods also have a pH ranging from about 4.5 to about 6.5. This pH range finds support in the specification at page 8, lines 29-30, among other places, and appears in independent claims 38, 53, and 65.

Claims 40, 55, and 61 each recite a cyclohexyl radical at the R^4 position of the 1-hydroxy-2-pyridone. This radical appears, among other places, in the specification at page 4, lines 1-3.

Claims 41, 56, and 62 add an octyl radical to the R^4 position of the 1-hydroxy-2-pyridone. Octyl radicals of the recited formula are mentioned on page 4, line 20, and in original claim 4.

Claims 42, 57, 63 include three specific 1-hydroxy-2-pyridones, salts thereof, or mixtures of any of these species. The named 1-hydroxy-2-pyridones appear in the specification on page 4, lines 10 and 19-20, and in original claim 5. Salts thereof appear in the specification on page 4, lines 31-32.

Claims 48, 58, and 64 each add at least one additional surfactant. Support for the additional surfactant appears, among other places, in the specification at page 5, line 37 through page 6, line 16.

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Independent claims 53 and 59 recite at least one keratolytic agent. Substances having a keratolytic action are mentioned on page 8, lines 5-6.

Claims 54 and 60 recite sulfur, salicylic acid, and enzymes, also appearing on page 8, lines 5-6.

Independent claims 65 and 66 include lactic acid, which is listed among the ingredients of Example 7 on page 12.

VI. Issues

A. Whether claims 38-39, 41-42, 48, 53-54, and 56-66 are non-obvious and patentable under 35 U.S.C. § 103(a) over *Lange,* U.S. Pat. No. 5,132,107, alone, or in view of *Durrant et al.,* U.S. Pat. No. 4,699,924.

B. Whether claims 40 and 55 are non-obvious and patentable under 35 U.S.C. § 103(a) over *Lange* and *Durrant et al.,* in further view of *Saint-Leger,* U.S. Pat. No. 5,650,145.

VII. Grouping Of Claims

Claims 38, 41, 42, and 48 stand or fall together.

Claim 39 stands alone.

Claims 40, 55, and 61 each stand alone and separately from each other.

Claims 53, 54, 56, 57, and 58 stand or fall together.

Claims 59, 60, 62, 63, and 64 stand or fall together.

Claim 65 stands alone.

Claim 66 stands alone.

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VIII. Argument

Claims 38-39, 41-42, 48, 53-54, and 56-66 stand rejected under 35 U.S.C. §§ 102(b)[1]/103(a) as allegedly being obvious over *Lange* alone, or in view of *Durrant et al.* Final Office Action dated July 18, 2002, at page 2. Appellants respectfully request that this rejection be reversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. M.P.E.P. § 2143.

The Federal Circuit has held that evidence of a teaching, suggestion, or motivation to combine may flow from the references themselves, from the knowledge of one of ordinary skill in the art, or from the nature of the problem, but may not flow from Applicant's disclosure. *See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996), *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d (BNA)

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1 While the wording of the final rejection relates clearly to § 103 obviousness, the Examiner has also referred to § 102(b). This causes some confusion as to the basis of the rejection. Although Appellants do not believe that an anticipation rejection was intended, Appellants wish to make clear that any anticipation rejection over *Lange* cannot stand. In the Examiner's words, "*Lange* teaches most of the elements required by [Appellants'] claims except the surfactant." Final Office Action at page 3. Each rejected claim requires "at least one surfactant." Since anticipation requires " 'each and every element as set forth in the claim [to be] found, either expressly or inherently described, in a single prior art reference[,]' " *Lange* fails to anticipate Appellants' claims. M.P.E.P. § 2131 (quoting *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d (BNA) 1051, 1053 (Fed. Cir. 1987).). To the extent that an anticipation rejection can be construed from the record, Appellants respectfully request that this rejection be reversed.

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1438, 1442 (Fed. Cir. 1991). Importantly, this evidence of a teaching, suggestion, or motivation to combine must be "clear and particular." *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d (BNA) 1614, 1617 (Fed Cir. 1999).

A. The Claims Are Patentable over *Lange* Alone.

Applying this standard, Appellants' claims are patentable over *Lange* alone. The Examiner has admitted as much. "This examiner agreed on that the Lange reference has defect." Interview Summary dated October 1, 2002. Nonetheless, Appellants address the obviousness rejection over *Lange* alone, to explain why the defects of *Lange* are not solved by resorting to *Durrant et al.* or *Saint-Leger et al.*

Lange discloses two compositions for the sequential treatment of the hair and scalp, with the goal of controlling dandruff and similar scale forming conditions. *See Lange* at col. 1, ll. 13-16. The first composition, or Phase I, has a neutral or weakly alkaline pH of 7.5 to 8.5 and contains detergents. *See id.* at col. 2, ll. 13-51; col. 3, ll. 57-62. *Lange's* second composition, Phase II, has an acidic pH and is applied after the first composition is rinsed out of the hair. *See id.* at col. 2, ll. 47-51.

The rejection over *Lange* fails, at least because there is no motivation to make the Examiner's modification of *Lange,* picking and choosing certain ingredients of Phase I to combine in Phase II. The modification appears in the Final Office Action at page 3:

> Thus, Lange teaches most of the elements required by the claims except the surfactant. Even though Lange does not express the term 'surfactant', it would have been obvious, however, to one of ordinary skill in the art to add a surfactant into the said Lange's second phase composition to enhance rinsing effects as suggested at column 6, lines 53-55.

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This bald assertion goes against the express teachings of *Lange*. *Lange* states, in column 2, lines 15-20, that detergents are not to be added to the second phase. In *Lange's* treatment, "the hair is washed with a detergent composition [Phase I] and after rinsing out this is treated consecutively with a separately applicable composition [Phase II] with an acid pH *in the absence of detergents,* by which microbial growth is inhibited through both treatments" (emphasis added).

Lange also teaches that an acidic composition comprising a soap is not feasible.

> To a limited extent shampoo compositions with an acid pH (for instance by including citric acid) are already known, but it has been found that soaps are not well suited for making lower pH products. Thus the simultaneous action of the two previously mentioned compositions included in one shampoo is *practically not feasable* [sic].

Lange at col. 2, ll. 55-62 (citation omitted; emphasis added). It is well-known that detergents contain surfactants.[2] These strong statements against using soaps and detergents in an acidic composition would clearly discourage one of ordinary skill in the art from adding any soaps or detergents to *Lange's* second phase composition. Thus, *Lange* expressly steers one of ordinary skill in the art away from adding surfactants to the second phase composition. Consequently, *Lange* teaches away from Appellants' claimed invention.

Moreover, the "rinsing effects" alleged by the Examiner indicate a misunderstanding of the cited passage of *Lange*. At column 6, lines 53-55, *Lange* teaches a two-compartment container for disclosed compositions. In so doing, *Lange* refers to the second phase composition as "the rinsing liquid (phase II)." This Phase II

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2 "Detergent" is defined as: "A synthetic cleansing agent resembling soap in the ability to emulsify oil and hold dirt, and containing surfactants which do not precipitate in hard water; may also contain protease enzymes and whitening agents." McGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS 519 (4th ed. 1989).

composition is never disclosed as having "rinsing effects" which might be enhanced by including surfactants as suggested by the Examiner; rather, this composition is an acidic rinse designed to act as an astringent to close up the microscopic structure of the skin. *See Lange* at col. 3, ll. 3-35. This would not work with surfactants, as *Lange* notes.

Other disclosures of *Lange* do not support the Examiner's alleged *prima facie* case. In a telephonic discussion held with the Examiner in early October, 2002, the Examiner indicated reliance on claim 15 of *Lange*. This claim provides that piroctone olamine, a 1-hydroxy-2-pyridone salt, is present in both the first phase and second phase compositions. Phase I does not have the pH range to anticipate or render obvious the claimed invention. Even if a 1-hydroxy-2-pyridone is present in the second phase composition of *Lange,* the Examiner has not shown how it would have been obvious to add a surfactant to that second phase composition to obtain anything resembling the compositions of Appellants' claimed methods.

Finally, Appellants have proceeded against the accepted wisdom in the art, as articulated by *Lange* at column 2, lines 55-62. Specifically, they have shown that a combination of soaps or detergents in one composition having a lower pH, among other ingredients, is, in fact, practically feasible. *Lange* teaches away from this invention. Evidence of proceeding contrary to accepted wisdom is strong evidence of non-obviousness. *See In re Hedges,* 783 F.2d 1038, 1041, 228 U.S.P.Q. (BNA) 685, 687 (Fed. Cir. 1986).

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B. The Claims Are Patentable over *Lange* in view of *Durrant et al.*

Durrant et al. does not correct the deficiencies of *Lange*. The *prima facie* case relying on these two documents fails, for at least three reasons.

First, the Examiner's combination of *Lange* and *Durrant et al.* lacks motivation because it would improperly change the principle of operation of *Lange's* treatment. The Examiner alleges that *Lange's* Phase II composition can be used as a single phase treatment. Specifically, the Examiner chooses only those ingredients of *Lange's* two-phase treatment and *Durrant's* compositions that approximate Appellants' claimed invention and combines them in a single composition. "One would have been motivated to do so [make the asserted combination] to make the cost-effective product when it combines in *one product* and improve the compliance that leads to higher therapeutic effects." Final Office Action at pages 3-4 (emphasis added). Moreover, "the method of treating seborrheic dermatitis could be achieved regardless the first phase composition, especially could be achieved by any cleansing activity in daily life." *Id.* at page 4. This line of analysis proceeds contrary to established law, because it changes the principle of operation of *Lange's* two-step treatment. *See* M.P.E.P. § 2143.01.

Contrary to the Examiner's interpretation, *Lange* requires both Phase I and Phase II compositions to be used in the disclosed treatment, and insists on keeping these two compositions separate.

> The two formulations of the two-phase shampoo are used in combination and they are suitably packed together but separately, on the one hand because both compositions may not be mixed without loss of effectivity and on the other hand because the synergistic effect of the components used in both liquids is only obtained if they are used one directly after the other!

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Lange at col. 6, ll. 18-24 (exclamation in original). The combination proposed by the Examiner, therefore, would change the manner in which *Lange's* treatment would work. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." M.P.E.P. § 2143.01 (*citing In re Ratti* 270 F.2d 810, 123 U.S.P.Q. (BNA) 349 (C.C.P.A. 1959).).

Second, there is no motivation to combine the teachings of these documents, because *Lange* and *Durrant et al.* employ two different methods of treatment. *Lange* contemplates a brief, shampoo-like treatment that is rinsed out of the hair soon after application. To illustrate, *Lange* teaches that a broad spectrum of activity of the ingredients "is of importance because of the relatively short period of duration of a shampoo rinsing treatment compared with a long lasting therapy." *Lange* at col. 5, l. 68 to col. 6, l. 2. *Durrant et al.*, on the other hand, contemplates a long lasting therapy, for example, in the form of a cream that is left on the skin and not rinsed off. To measure effectiveness of topical delivery of an acid, *Durrant's* cream was applied to human volunteers and skin pH was measured over four hours. *Durrant et al.* at col. 11, ll. 19-40. Nowhere does *Durrant et al.* teach or suggest that the disclosed compositions, or ingredients thereof, could be useful in a shampoo-like treatment such as that contemplated by *Lange*. These two different skin treatments, therefore, are remote enough from each other to preclude assuming any motivation to combine them. In a situation analogous in this respect, the Court of Customs and Patent Appeals stated: "we find nothing in the disclosure of Jepson's coffee maker gasket to suggest that any part of it has applicability to shaft seals. The two arts are at least somewhat remote from each other even if they both involve sealing." *In re Ratti,* 270 F.2d at 813, 123

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U.S.P.Q. at 352. In contrast, the motivation to combine must be shown by "clear and particular" evidence (*In re Dembiczak,* 175 F.3d at 999, 50 U.S.P.Q.2d at 1617), and here it is not.

To illustrate the remoteness of these two arts, *Durrant's* disclosed compositions are said to represent "a totally new type of product" (col. 1, ll. 17-18), that imparts a greater affinity for human skin to an amphiphilic compound "than would be the case if the amphiphilic compound had been incorporated into a normal oil-in-water emulsion" (col. 2, ll. 13-15). *Durrant et al.* accomplishes this with an emulsifier that is "a special normally solid emulsifier capable of forming a gel phase." *Durrant et al.* at col. 1, ll. 18-20. *Durrant et al.* narrowly defines the emulsifier,

> which is normally solid at 20° C, which has an average HLB value of from 5 to 11, and which is capable with water of forming a gel phase having an X-ray reflection of from 0.37 to 0.44 nm and which permits substantially no co-crystallisation therewith of the amphiphilic compound.

Durrant et al. at col. 1, ll. 40-46. Thus, *Durrant's* emulsifier is not a "normal" emulsifier capable of forming a "normal" oil-in-water emulsion. In contrast, *Lange* mentions a "hydrophilic alcohol gel" in his first claim, formed with compounds not taught or suggested as useful in *Durrant's* compositions. *See Lange* at col. 7, l. 38 (listing hydroxypropylcellulose as a "gelling agent"), and col. 8, l. 22 (listing methylcellulose as a "gelling agent"). *Durrant's* words teach the skilled artisan to use his special solid emulsifier cautiously and with skepticism. This skepticism points out the lack of motivation to make the Examiner's asserted combination.

A much closer rejection was reversed by the Federal Circuit in *In re Geiger,* 815 F.2d 686, 2 U.S.P.Q.2d (BNA) 1276 (Fed. Cir. 1987). The *Geiger* applicants claimed a method of inhibiting scale formation and corrosion in a cooling water system using a

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composition comprising three ingredients. The references individually taught combinations of perhaps two of applicants' three ingredients in compositions for preventing scale in boiling or cooling water systems, with all three ingredients being disclosed by several references. Yet the Federal Circuit found no suggestion to combine all three ingredients in one composition for the purpose of inhibiting scaling and corrosion in a cooling water system. It was not enough that the three ingredients appeared in the prior art, even in compositions useful for the same purpose as applicants' claimed method. The court rejected the PTO's finding of a *prima facie* case of obviousness, stating, "At best, in view of these disclosures, one skilled in the art might find it obvious to try various combinations of these known scale and corrosion prevention agents. However, this is not the standard of 35 U.S.C. § 103." *In re Geiger,* 815 F.2d at 688, 2 U.S.P.Q.2d at 1278.

In the present case, Appellants reject the suggestion that it would have been obvious to try to mix *Durrant's* "totally new type of product," or any "special" ingredient thereof, with *Lange's* two-phase treatment to obtain Appellants' claimed method of treating seborrheic dermatitis. It is only with hindsight reasoning that the Examiner can find the necessary motivation in these cited documents.

The Federal Circuit has repeatedly stated that to make a *prima facie* case of obviousness, "particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Lee,* 277 F.3d 1338, 1343, 61 U.S.P.Q.2d (BNA) 1430, 1433 (Fed. Cir. 2002) (*citing In re Kotzab,* 217 F.3d 1365, 1371, 55 U.S.P.Q.2d (BNA) 1313, 1317 (Fed. Cir. 2000).). Here, the Examiner has made no particularized findings to show why a skilled artisan, without knowledge of Appellants'

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claimed invention, would have specifically chosen the ingredients of the compositions used in Appellants' claimed methods of treating seborrheic dermatitis.

Third, one of ordinary skill in the art would have no reasonable expectation of success in the combination. *Durrant et al.* teaches a very narrow class of special, solid emulsifiers. *Durrant et al.* at col. 1, ll. 40-46. Neither *Durrant et al.* nor *Lange* teach or suggest that shampoo-like treatments, such as those contemplated by *Lange*, could be operable with such emulsifiers. Thus, one of ordinary skill would not reasonably expect that *Lange's* Phase II composition, for example, would still function for its intended purpose while containing such emulsifiers. Accordingly, the *prima facie* case fails also for lack of a reasonable expectation of success. *See* M.P.E.P. § 2143.

1. Claims 38, 41, 42, and 48 Are Separately Patentable

Claims 38, 41, 42, and 48 are non-obvious over *Lange,* alone or in view of *Durrant et al.* These claims recite a method of treating seborrheic dermatitis by administering a composition comprising an active component consisting essentially of at least one 1-hydroxy-2-pyridone, further comprising at least one surfactant, and having a pH ranging from about 4.5 to about 6.5. *Lange* fails to render these claims obvious, for the reasons discussed above, and specifically because *Lange* teaches away from combining at least one surfactant in one composition at a pH ranging from about 4.5 to about 6.5. *See, for example, Lange* at col. 2, l. 18.

These claims are also non-obvious over *Lange* in view of *Durrant et al.,* in addition to the reasons discussed above, because the compositions recited in these claims comprise an active component *consisting essentially* of at least one 1-hydroxy-2-pyridone. *Durrant et al.,* in addition to an emulsifier, requires an "activity enhancer." To

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the extent that such an activity enhancer would materially change the properties of Appellants' claimed active component, the Examiner has not shown how the skilled artisan would know to choose *Durrant's* required emulsifier while excluding *Durrant's* equally required activity enhancer.

2. Claim 39 Is Separately Patentable

Claim 39 is separately patentable over the two cited documents. This claim recites a method for treating seborrheic dermatitis by administering a composition comprising at least one 1-hydroxy-2-pyridone and at least one surfactant. Claim 39 is non-obvious over *Lange,* as discussed above, and also because a skilled artisan would have to pick and choose to obtain the method of claim 39. To cobble together the method recited in claim 39, one of ordinary skill in the art would have to pick and choose from *Lange's* disclosure, while ignoring the teaching of what *Lange* actually used to treat seborrheic dermatitis in Example I. In that example, *Lange* employs coal tar distillate to treat seborrheic dermatitis. *Lange* at cols. 6-7. Such picking and choosing is improper within the framework of an obviousness analysis. *See In re Wesslau,* 353 F.2d 238, 241, 147 U.S.P.Q. (BNA) 391, 393 (C.C.P.A. 1965).

Claim 39 is also non-obvious over *Lange* in view of *Durrant et al.,* for the reasons set forth above, and specifically because the motivation fails. *Durrant et al.* mentions an anti-dandruff hair cream containing Octopirox at column 14, line 63, but does not mention seborrheic dermatitis anywhere. The Examiner extrapolates *Durrant's* disclosure to find a method of treating seborrheic dermatitis (which is a disorder distinct from dandruff), even though the evidence for doing so is less than "clear and particular,"

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as required by the Federal Circuit. *See In re Dembiczak,* 175 F.3d at 999, 50 U.S.P.Q.2d at 1617.

3. Claims 53, 54, 56, 57, and 58 Are Separately Patentable

Claims 53, 54, 56, 57, and 58 are non-obvious over *Lange* alone, for reasons in addition to those discussed above. These claims recite methods for treating seborrheic dermatitis by administering compositions comprising at least one 1-hydroxy-2-pyridone, at least one surfactant and at least one keratolytic agent, with the composition having a pH ranging from about 4.5 to about 6.5. *Lange* claims a keratolytic agent in basic Phase I in claim 14. However, the combination of a surfactant at an acidic pH in one composition is specifically taught against at column 2, lines 13-20 and 55-63. Thus, one of ordinary skill in the art would not be motivated to combine a surfactant with a keratolytic agent in a composition having an acidic pH, based on the disclosure of *Lange.*

These claims are also non-obvious over *Lange* in view of *Durrant et al.,* in addition to the reasons given above, because these documents do not teach or suggest the claimed method. Specifically, *Durrant et al.* teaches a keratolytic foot lotion at column 15, but no motivation can be found to augment *Lange's* two-phase hair shampoo with this foot composition of *Durrant et al.*

4. Claims 59, 60, 62, 63, and 64 Are Separately Patentable

Claims 59, 60, 62, 63, and 64 recite methods for treating seborrheic dermatitis by administering compositions comprising at least one 1-hydroxy-2-pyridone, at least one surfactant, and at least one keratolytic agent. These claims are non-obvious over

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Lange alone, generally for the reasons set forth above, and specifically because the skilled artisan would have to pick and choose from among *Lange's* disclosures, and ignore what *Lange* actually uses to treat seborrheic dermatitis in Example I. *See Lange* at cols. 6-7. This picking and choosing is impermissible. *See In re Wesslau,* 353 F.2d at 241, 147 U.S.P.Q. at 393.

These claims are also non-obvious over *Lange* in view of *Durrant et al.*, in addition to the reasons given above, since these documents do not teach or suggest the claimed methods. Neither document, for example, teaches or suggests the utility of a keratolytic agent in addition to an antifungal agent in a composition for the treatment of seborrheic dermatitis. Accordingly, such a method would be obvious to try, at best.

5. Claim 61 Is Separately Patentable

Claim 61 recites the method of claim 59, in which the 1-hydroxy-2-pyridone comprises a cyclohexyl radical in the R^4 position. Notably, this claim would stand entirely on its own if rewritten in independent form. This claim is non-obvious over *Lange,* as discussed above, and also because *Lange* does not teach or suggest a cyclohexyl radical at the R^4 position of the 1-hydroxy-2-pyridones. *See Lange* at col. 4, ll. 46-48.

Claim 61 is also non-obvious over *Lange* in view of *Durrant et al.,* among other reasons, since *Durrant et al.* does not teach or suggest a cyclohexyl radical at the R^4 position of the 1-hydroxy-2-pyridones, either. *See Durrant et al.* at col. 3, ll. 14-15.

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6. Claims 65 and 66 Are Separately Patentable

Claims 65 and 66 are non-obvious over *Lange* alone, and in view of *Durrant et al.* for reasons further to those set forth above. Claim 66 recites a method for treating seborrheic dermatitis by administering a composition comprising at least one 1-hydroxy-2-pyridone, at least one surfactant, and lactic acid. This claim is non-obvious over *Lange* alone, in addition, because *Lange* does not teach or suggest a composition comprising at least one surfactant and lactic acid. *Lange* discloses lactic acid at column 5, line 26, and column 8, line 12, but only for the Phase II composition, which expressly excludes detergents, and therefore, surfactants. *See Lange* at col. 2, l. 18.

Claim 65 is patentable over *Lange* alone. Claim 65 independently recites a method similar to that of claim 66, but the composition of claim 65 has a pH ranging from about 4.5 to about 6.5.[3] *Lange* simply does not teach or suggest the combination of a surfactant and lactic acid in a composition having a pH ranging from about 4.5 to about 6.5. *See Lange* at col. 2, l. 18.

Claims 65 and 66 are non-obvious over *Lange* in view of *Durrant et al.*, for the reasons given above, and also because these documents do not teach or suggest a composition comprising at least one surfactant and lactic acid. As to claim 65, these documents do not teach or suggest Appellants' claimed pH for such a composition, either. *Durrant et al.* does not mention lactic acid, so adds nothing to the disclosure of *Lange* for the rejection of these claims.

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3 The definition of the Ar radical in the 1-hydroxy-2-pyridone also differs between claims 65 and 66.

C. Claims 40 and 55 Are Separately Patentable over *Lange, Durrant et al.*, and *Saint-Leger*

Claims 40 and 55 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over *Lange* and *Durrant et al.* in further view of *Saint-Leger*. Final Office Action at page 4. *Saint-Leger* allegedly teaches the cyclohexyl radical of these two rejected claims. *See id.* Appellants respectfully request that this rejection be reversed.

The Examiner's reasoning overstates the teaching of *Saint-Leger*: "Saint Leger teaches that Octopirox or Ciclopirox is effectively used in the treatment of seborrheic dermatitis (see column 2, lines 29-32)." Final Office Action at page 4. In fact, the cited passage merely teaches:

> Among the antifungal agents suitable for formulation according to the invention, particularly representative are . . . hydroxypyridone derivatives such as CICLOPIROX, i.e., 6-cyclohexyl-1-hydroxy-4-methyl-2-(1H)-pyridone, or OCTOPIROX, i.e., 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridone."

Saint-Leger at col. 2, lines 25-32. Effective use of these compounds to treat seborrheic dermatitis finds no mention in this passage.

Saint-Leger does not cure the deficiencies of *Lange* in view of *Durrant et al.* Even if the substitution proposed by the Examiner can be made, it does not cure the lack of motivation to combine the cited documents. *Lange* teaches away from adding a detergent to the Phase II composition, and requires a two-composition treatment, contrary to the Examiner's assertion that a one-composition treatment would be obvious.

The Examiner asserts, however, that motivation can be found, since the three cited documents "are drawn to the same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which

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applicant is concerning. MPEP 2141.01(a)." Final Office Action at page 4. Appellants respectfully submit that the articulated standard and the cited section of the M.P.E.P. relate to determining whether a reference is analogous art to the claimed invention. This section does not articulate the standard for finding motivation. To illustrate, the prior art references in *In re Geiger* all related to inhibiting scale formation in boiling or cooling water systems, while the claimed invention related to inhibiting scale formation in cooling water systems. *In re Geiger,* 815 F.2d at 687, 2 U.S.P.Q.2d at 1277. Thus, at least some of those references were clearly analogous art to the claimed invention. However, the motivation analysis goes beyond merely finding that cited documents are analogous art to the claimed invention. *Compare* M.P.E.P. §§ 2141.01(a) and 2143.01. And in *In re Geiger,* the Federal Circuit found that motivation was lacking, in spite of the analogous nature of the references. *See In re Geiger,* 815 F.2d at 688, 2 U.S.P.Q.2d at 1278. Once analogous art is found, a *prima facie* case of obviousness requires that "particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Lee,* 277 F.3d at 1343, 61 U.S.P.Q.2d at 1433. In the present case, motivation is lacking, whether or not *Lange, Durrant et al.,* and *Saint-Leger* are analogous art to Appellants' claimed invention.

A closer look at claims 40 and 55 reveal their patentability over these three cited documents. Both claims 40 and 55 depend from claims reciting at least one surfactant and a pH ranging from about 4.5 to about 6.5, and so these limitations are included in these claims. The reasons why a composition having at least one surfactant and the claimed pH range are not obvious in view of *Lange* and *Durrant et al.* are given above. In addition, claim 40 comprises an active component consisting essentially of at least

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one 1-hydroxy-2-pyridone. *See* claim 38, upon which claim 40 depends. *Saint-Leger* requires at least one antifungal agent and at least one halogenated antibacterial agent. *See Saint-Leger* at col. 1, ll. 9-13. To the extent that *Saint-Leger's* antibacterial agent would materially change the properties of Appellants' active component, it has not been shown how one of ordinary skill in the art would borrow *Saint-Leger's* required antifungal agent while leaving behind *Saint-Leger's* equally required antibacterial agent.

This rejection, therefore, should be reversed.

D. *Fitzpatrick's Dermatology* Does Not Aid the Examiner

To rebut Appellants' argument that dandruff is not the same as seborrheic dermatitis, the Examiner relies on the teaching of *Fitzpatrick's Dermatology*. *See* Final Office Action at page 5 (*citing Fitzpatrick's Dermatology in General Medicine,* 5th ed., CD-ROM, Ch. 126 (1999).). In citing this document, the Examiner misstates its teachings. First, the Examiner asserts that "Seborrheic dermatitis is manifested by fluffy white dandruff (see page 8/17) and effectively treated by ciclopiroxolamine (see page 10/17)." Final Office Action at page 5 (*citing Fitzpatrick's Dermatology*). This overstatement should be tempered by noting what is actually taught: "Asymptomatic, fluffy white dandruff of the scalp represents the mild end of the spectrum of seborrheic dermatitis and has been referred to as *pityriasis sicca*." *Fitzpatrick's Dermatology* at page 8 of 17. This statement does not support the implied position taken by the Examiner, that a treatment of dandruff necessarily teaches a treatment of seborrheic dermatitis. Treating symptoms often does not treat the underlying disorder. For example, cough medicine may treat a cough, but it does not treat the underlying cold

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virus infection. In addition, the Examiner's citation to page 10 of 17 actually helps Appellants. That page states:

> Good results [in the treatment of seborrheic dermatitis] are achieved with topical application of antifungal agents, ... In these trials, however, only ketoconazole or itraconazole were studied; other [compounds] such as . . . ciclopiroxolamine *may* also be effective.

Fitzpatrick's Dermatology at page 10 of 17 (footnotes omitted; emphasis added). Appellants note that this document, dated after their priority date, only speculates that ciclopirox olamine, a well-known 1-hydroxy-2-pyridone salt, could treat seborrheic dermatitis. On the basis of *Fitzpatrick's Dermatology,* one of ordinary skill in the art might have found such a treatment to be merely obvious to try, as late as 1999.

The Examiner further overstates the teachings of the cited documents. "It [*Fitzpatrick's Dermatology*] also teaches that seborrheic dermatitis is eczema (synonym) where each patentee in the cited reference (supra) teaches their patented antidandruff composition is effective in eczema condition as well (see Durrant, for example)." Final Office Action at 5. This statement is erroneous, first of all, because *Fitzpatrick's Dermatitis* refers to a particular condition, *eczéma flannellaire*, not to all eczema, and the relationship between *eczéma flannellaire* and eczema is not clear. *See Fitzpatrick's Dermatology* at page 2 of 17. Second, *Lange* and *Saint-Leger* do not mention eczema at all. Third, *Durrant et al.* does not teach that an anti-dandruff composition is useful for treating eczema. Rather, *Durrant et al.* uses erythromycin to treat eczema (col. 12, ll. 50-69) and octopirox to treat dandruff (col. 14, ll. 52-69).

Finally, Appellants note that the publication date of *Fitzpatrick's Dermatology* precludes it from being prior art to the present application. Appellants have cited it

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merely to distinguish dandruff from seborrheic dermatitis. *See* Amendment filed April 24, 2002, at page 20.

In sum, Appellants assert that *Fitzpatrick's Dermatology* does not support the *prima facie* case, nor does it rebut Appellants' simple distinction of dandruff from seborrheic dermatitis. In fact, this document helps Appellants by showing that treatment of seborrheic dermatitis with a 1-hydroxy-2-pyridone was still guesswork, long after their priority date.

IX. Conclusion

If any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, Appellants respectfully request such extension. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 that are not enclosed herewith, including any fees required for any extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 16, 2002

By: Jeremy M. Stipkala
Jeremy M. Stipkala
Reg. No. 44,359

Post Office Address (to which correspondence is to be sent)

Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, D.C. 20005
(202) 408-4000

Enclosures:
Appendix A (Claims after Amendment filed April 24, 2002)
Appendix B (Claims after Amendment under 37 C.F.R. § 1.116 filed herewith)

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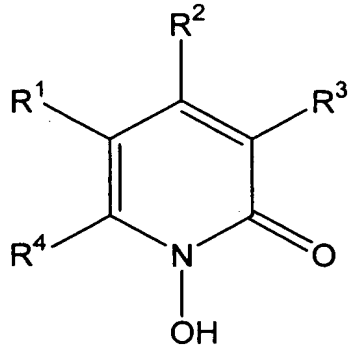
APPENDIX A

Pending claims 38-42, 48, and 53-66 appear listed below.

38. (Thrice Amended 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising:

(A) an active component consisting essentially of at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:

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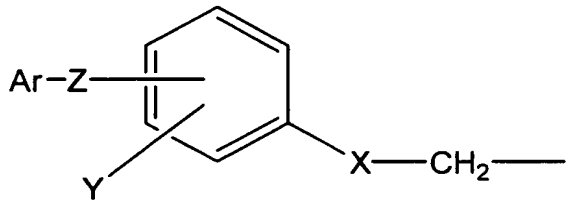

(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

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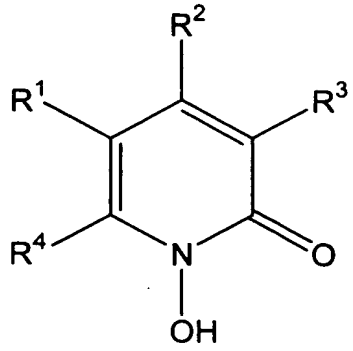
Ar is an aromatic ring system having one or two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy; and

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; and

wherein the composition has a pH ranging from about 4.5 to about 6.5.

39. (Thrice Amended 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition which comprises:

(A) at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



(I)

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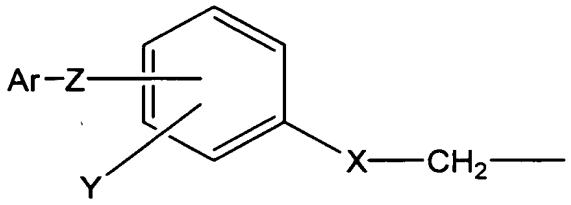
where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

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in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy, and wherein Ar is a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether; and

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants.

40. (Twice Amended 9/18/01) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 38 in which the at least one 1-hydroxy-2-pyridone of formula I comprises a cyclohexyl radical in the R^4 position.

41. (Twice Amended 9/18/01) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 38 in which the at least one 1-hydroxy-2-pyridone of formula I comprises an octyl radical of the formula $-CH_2-CH(CH_3)-CH_2-C(CH_3)_3$ in the R^4 position.

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42. (Twice Amended 9/18/01) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 38 in which the pharmaceutical composition comprises 1-hydroxy-4-methyl-6-(4-(4-chlorophenoxy)phenoxymethyl)-2(1H)pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2(1H)pyridone, or 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2(1H)pyridone, or a pharmaceutically acceptable salt of any of the foregoing, or a mixture of any of the foregoing.

48. (Twice Amended 9/18/01) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 38 in which the pharmaceutical composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants.

53. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising:

(A) at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:

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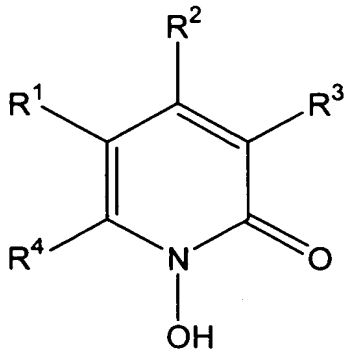
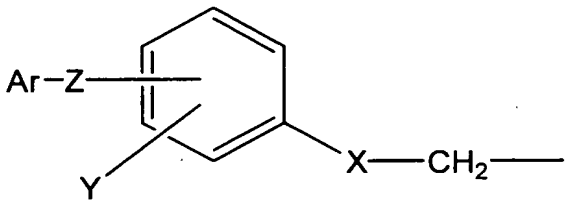


(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

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(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having one or two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy;

(B) is at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; and

(C) is at least one keratolytic agent; and

wherein the composition has a pH ranging from about 4.5 to about 6.5.

54. (New 4/24/02) The method of claim 53, wherein the keratolytic agent is one or more of the agents selected from the group consisting of sulfur, salicylic acid, and enzymes.

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55. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 53 in which the at least one 1-hydroxy-2-pyridone of formula I comprises a cyclohexyl radical in the R^4 position.

56. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 53 in which the at least one 1-hydroxy-2-pyridone of formula I comprises an octyl radical of the formula $-CH_2-CH(CH_3)-CH_2-C(CH_3)_3$ in the R^4 position.

57. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 53 in which the pharmaceutical composition comprises 1-hydroxy-4-methyl-6-(4-(4-chlorophenoxy)phenoxymethyl)-2(1H)pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2(1H)pyridone, or 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2(1H)pyridone, or a pharmaceutically acceptable salt of any of the foregoing, or a mixture of any of the foregoing.

58. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 53 in which the pharmaceutical composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants.

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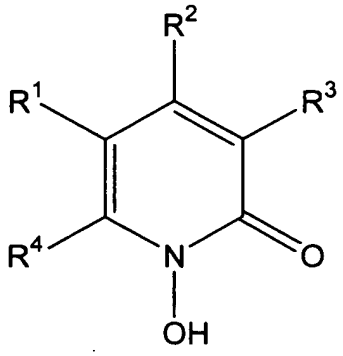
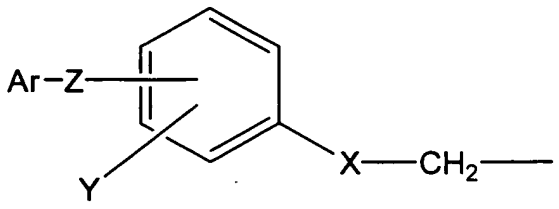
59. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition which comprises:

(A) at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

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Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having two rings, the aromatic ring stem being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy, and wherein Ar is a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether;

B) is at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; and

(C) is at least one keratolytic agent.

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60. (New 4/24/02) The method of claim 59, wherein the keratolytic agent is one or more of the agents selected from the group consisting of sulfur, salicylic acid, and enzymes.

61. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 59 in which the at least one 1-hydroxy-2-pyridone of formula I comprises a cyclohexyl radical in the R^4 position.

62. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 59 in which the at least one 1-hydroxy-2-pyridone of formula I comprises an octyl radical of the formula $-CH_2-CH(CH_3)-CH_2-C(CH_3)_3$ in the R^4 position.

63. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 59 in which the pharmaceutical composition comprises 1-hydroxy-4-methyl-6-(4-(4-chlorophenoxy)phenoxymethyl)-2(1H)pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2(1H)pyridone, or 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2(1H)pyridone, or a pharmaceutically acceptable salt of any of the foregoing, or a mixture of any of the foregoing.

64. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 59 in which the pharmaceutical

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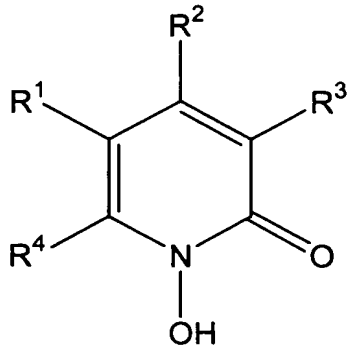
composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants.

65. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising:

(A) an active component consisting essentially of at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:

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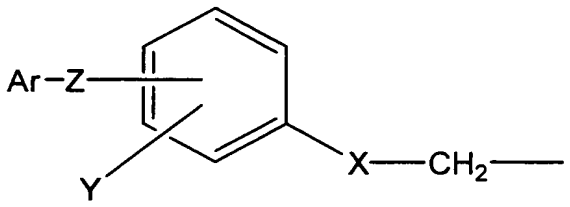

(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

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Ar is an aromatic ring system having one or two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy;

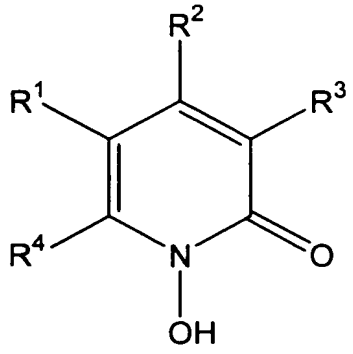
(B) is at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants;

(C) is lactic acid; and

wherein the composition has a pH ranging from about 4.5 to about 6.5.

66. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition which comprises:

(A) at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



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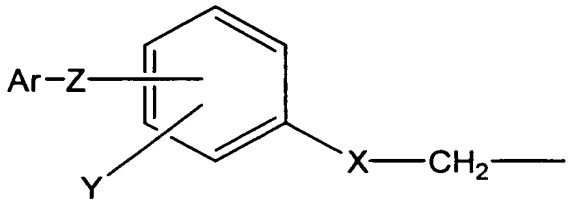
where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

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in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy, and wherein Ar is a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether;

(B) is at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; and

(C) is lactic acid.

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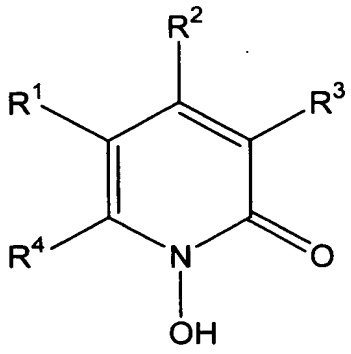
APPENDIX B

Pending claims 38-42, 48, and 53-66 appear listed below.

38. (Thrice Amended 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising:

(A) an active component consisting essentially of at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:

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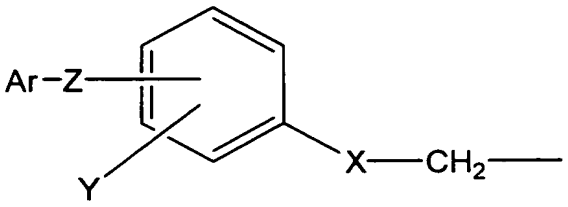

(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

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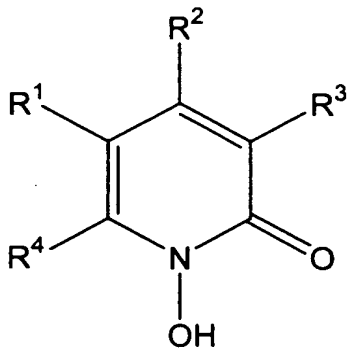
Ar is an aromatic ring system having one or two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy; and

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; and

wherein the composition has a pH ranging from about 4.5 to about 6.5.

39. (Thrice Amended 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition which comprises:

(A) at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



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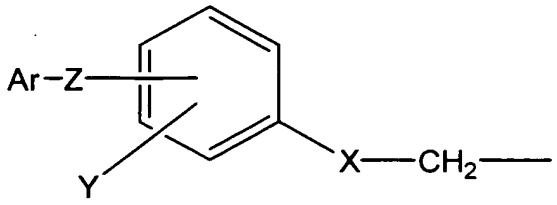
where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

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in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy, and wherein Ar is a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether; and

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants.

40. (Twice Amended 9/18/01) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 38 in which the at least one 1-hydroxy-2-pyridone of formula I comprises a cyclohexyl radical in the R^4 position.

41. (Twice Amended 9/18/01) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 38 in which the at least one 1-hydroxy-2-pyridone of formula I comprises an octyl radical of the formula $-CH_2-CH(CH_3)-CH_2-C(CH_3)_3$ in the R^4 position.

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42. (Twice Amended 9/18/01) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 38 in which the pharmaceutical composition comprises 1-hydroxy-4-methyl-6-(4-(4-chlorophenoxy)phenoxymethyl)-2(1H)pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2(1H)pyridone, or 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2(1H)pyridone, or a pharmaceutically acceptable salt of any of the foregoing, or a mixture of any of the foregoing.

48. (Twice Amended 9/18/01) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 38 in which the pharmaceutical composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants.

53. (Once Amended 12/16/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising:

(A) at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:

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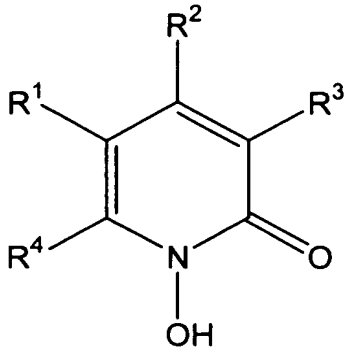
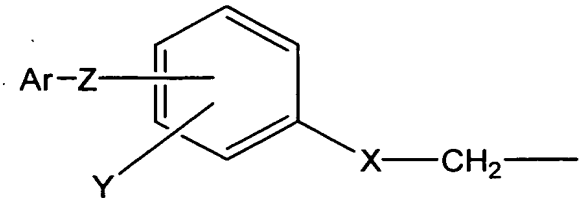


(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

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(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having one or two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy;

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; and

(C) at least one keratolytic agent; and

wherein the composition has a pH ranging from about 4.5 to about 6.5.

54. (New 4/24/02) The method of claim 53, wherein the keratolytic agent is one or more of the agents selected from the group consisting of sulfur, salicylic acid, and enzymes.

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55. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 53 in which the at least one 1-hydroxy-2-pyridone of formula I comprises a cyclohexyl radical in the R^4 position.

56. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 53 in which the at least one 1-hydroxy-2-pyridone of formula I comprises an octyl radical of the formula $-CH_2-CH(CH_3)-CH_2-C(CH_3)_3$ in the R^4 position.

57. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 53 in which the pharmaceutical composition comprises 1-hydroxy-4-methyl-6-(4-(4-chlorophenoxy)phenoxymethyl)-2(1H)pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2(1H)pyridone, or 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2(1H)pyridone, or a pharmaceutically acceptable salt of any of the foregoing, or a mixture of any of the foregoing.

58. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 53 in which the pharmaceutical composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants.

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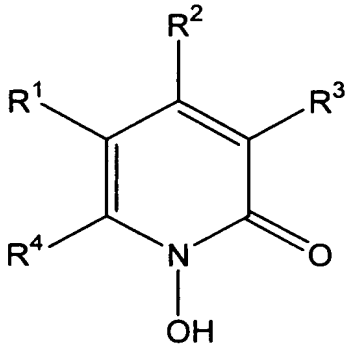
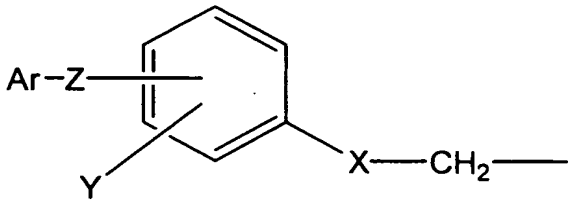
59. (Once Amended 12/16/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition which comprises:

(A) at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

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Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy, and wherein Ar is a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether;

B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; and

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(C) at least one keratolytic agent.

60. (New 4/24/02) The method of claim 59, wherein the keratolytic agent is one or more of the agents selected from the group consisting of sulfur, salicylic acid, and enzymes.

61. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 59 in which the at least one 1-hydroxy-2-pyridone of formula I comprises a cyclohexyl radical in the R^4 position.

62. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 59 in which the at least one 1-hydroxy-2-pyridone of formula I comprises an octyl radical of the formula $-CH_2-CH(CH_3)-CH_2-C(CH_3)_3$ in the R^4 position.

63. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 59 in which the pharmaceutical composition comprises 1-hydroxy-4-methyl-6-(4-(4-chlorophenoxy)phenoxymethyl)-2(1H)pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2(1H)pyridone, or 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2(1H)pyridone, or a pharmaceutically acceptable salt of any of the foregoing, or a mixture of any of the foregoing.

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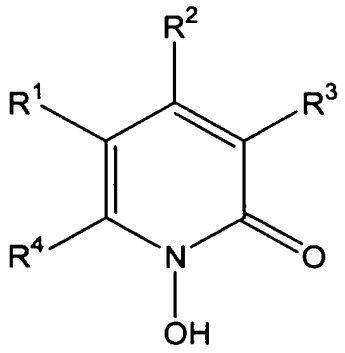
64. (New 4/24/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim 59 in which the pharmaceutical composition further comprises at least one additional surfactant chosen from anionic, cationic, nonionic, and amphoteric surfactants.

65. (Once Amended 12/16/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising:

(A) an active component consisting essentially of at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:

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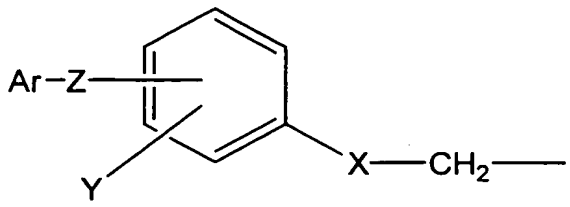

(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

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Ar is an aromatic ring system having one or two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy;

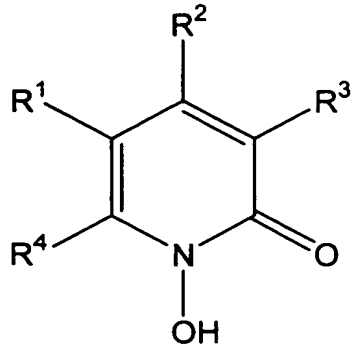
(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants;

(C) lactic acid; and

wherein the composition has a pH ranging from about 4.5 to about 6.5.

66. (Once Amended 12/16/02) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition which comprises:

(A) at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



(I)

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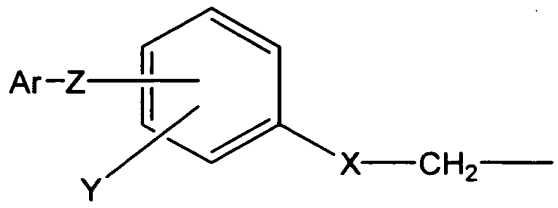
where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

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in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy, and wherein Ar is a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether;

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; and

(C) lactic acid.

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